

REMARKS

The specification has been amended to reflect that Application 09/541,374, which is the parent of the present application, issued as U.S. Patent No. 6,689,823.

Claims 15 and 20 have been cancelled.

Claims 38 and 39 have been added to further describe that which the Applicants regard as the invention. Support for new Claims 38 and 39 can be found at page 11, lines 19-22.

Claims 1 and 18 are amended to further describe the polymer matrix and the type of filler that is present in regions occupied by polymerized liquid component. Support for the amendments is found at page 9, line 28 through page 10, line 16 and page 6, lines 6-27.

Claim 1 has been further amended to recite "less than" instead of "less than about."

The remainder of this amendment is set forth under appropriate subheadings for the convenience of the Examiner.

Applicants' Invention

With respect to the claims under examination, Applicants' invention is related to nanocomposite surgical materials (e.g., bone cements, surgical plates, screws, implants, materials used in art restoration and in dental applications) that include a polymer matrix and a nanoencapsulated solid filler. The materials of the invention combine both, a small average filler diameter, i.e., less than 1000 nanometers (nm), and a filler distribution or dispersion within the polymer matrix, or regions thereof, such that filler aggregation, agglomeration or coalescence are reduced or minimized.

In one embodiment, a nanocomposite surgical material of the invention includes a polymer matrix and a nanoencapsulated solid filler. The polymer matrix is formed by polymerizing a liquid component and polymeric powder particles. At least a portion of the solid filler is present in regions occupied by polymerized liquid component, as discussed at page 9, line 28 to page 10, line 16 of the specification. Regions occupied by polymerized liquid component, are also referred to in the field as "inter-bead" matrix regions. A diagram, not drawn to scale, showing the bead (corresponding to polymeric powder particles) and inter-bead matrix

region (which includes dispersed solid filler), is enclosed as Exhibit 1, for the convenience of the Examiner.

Double Patenting Rejection

Claims 1-22 are rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 1-47 of U.S. Patent No. 6,689,823. A Terminal Disclaimer is being filed herewith to expedite prosecution by obviating the obviousness-type double patenting rejection. Submission of the Terminal Disclaimer should not be construed as an admission that Applicants agree to the Examiner's basis for this rejection.

Rejection of Claims 1-22 under 35 U.S.C. § 112, second paragraph

Claims 1-22 are rejected under 35 U.S.C. § 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. The Examiner stated that the phrase "less than about" is indefinite.

Independent Claim 1, the only claim to recite the phrase "less than about", has been amended to recite "less than" as recommended by the Examiner. As amended, it is believed that all claims are definite and meet the requirements under 35 U.S.C. § 112, second paragraph.

Rejection of Claims 1-8, 14 and 16-19 under 35 U.S.C. § 102(b)

Claims 1-8, 14 and 16-19 are rejected under 35 U.S.C. § 102(b) as anticipated by Podszun (U.S. Patent No. 4,617,327).

The Examiner stated that Podszun teaches the use of coated (or encapsulated) silica filler having a particle size of 20 nm in methyl methacrylate and polymethyl-methylacrylate polymer beads and teaches microfiller with a particle size of 5 to 700 nm.

Podszun teaches a solid particulate component for use in dental materials which is referred to in the cited document as a "filler". As discussed throughout the cited document and in particular at column 2, lines 8-26, this component includes an "inorganic core" that "consists of" inorganic particles with a particle size of 10 to 500 nm, a first shell of vinyl silane and a second shell of a (meth)acrylate polymer. To produce this component, the reference teaches silanizing the inorganic particles with a mixture of vinylsilane, water and acid in a first step,

followed by "encasing" the silanized inorganic particles with meth(acrylate) polymers, by polymerization, in a second step. Podszun, at column 2, lines 8-18. Formation of a dental material is taught in Example 4 of the reference. It includes kneading together the polymerized solid (meth)acrylate particles, that already encase the inorganic core, with other components; the resulting paste-like composition is pressed into teeth molds and hardened.

Applicants respectfully submit that in the material disclosed by Podszun, inorganic particles with a particle size of 10 to 500 nm are present as a core within the interior region of (meth)acrylate polymeric powder particles. There is no disclosure and no suggestion in Podszun for a material where the inorganic particles are outside the solid (meth)acrylate shell, such as in a region occupied by polymerized liquid component, as claimed by Applicants. Furthermore, the cited reference neither teaches nor suggests dispersing the inorganic particles within the polymer matrix to produce Applicants' claimed materials.

Applicants' claimed invention is directed to a nanocomposite surgical material that includes a polymer matrix and nanoencapsulated solid filler. The polymer matrix is formed by polymerizing (or curing) a liquid component, such as, for example, methyl methacrylate monomer, and polymeric powder particles. At least a portion of the filler is present in regions occupied by the polymerized liquid component.

Additionally, Podszun does not disclose or suggest fillers that deliver additional benefits as presently claimed by Applicants. There is no disclosure or suggestion in Podszun regarding a filler that has radio-opaque properties nor regarding a filler that includes a bioactive or pharmaceutical component, as presently claimed by Applicants.

Applicants respectfully submit that Claims 1-8, 14 and 16-19 are not anticipated by the teachings of Podszun. Reconsideration and withdrawal of this rejection are respectfully requested.

Rejection of Claims 1-8, 14 and 16-19 under 35 U.S.C. § 103(a)

Claims 1-8, 14 and 16-19 are also rejected, in the alternative, under 35 U.S.C. § 103(a) as obvious in view of Podszun.

The Examiner stated that the invention recites a powder composition, while Podszun teaches "a mixture of powder form [sic] of a nanoencapsulated solid filler and PMMA bead

polymer and methacrylate monomers in example 4.” The Examiner further states that it would have been obvious to one skilled in the art to store the powder and monomers in separate packages until use since such packages would provide easy mixing of various ratios of the powder and monomers.

This point does not remedy the deficiencies of Podszun. As discussed above, there is no disclosure and no suggestion in Podszun for a material where the inorganic particles are outside the solid (meth)acrylate shell, such as in a region occupied by polymerized liquid component, as claimed by Applicants. Furthermore, the cited reference neither teaches nor suggests dispersing the inorganic particles within the polymer matrix to produce Applicants’ claimed materials. Additionally, there is no disclosure and no suggestion of fillers that deliver additional benefits as presently claimed by Applicants.

Therefore, Claims 1-8, 14 and 16-19 meet the requirements of 35 U.S.C. § 103(a). Reconsideration and withdrawal of this rejection are respectfully requested.

Rejection of Claims 1-8 and 15-22 under 35 U.S.C. § 103(a)

Claims 1-8 and 15-22 are rejected under 35 U.S.C. § 103(a) as obvious over Podszun (U.S. Patent No. 4,617,327) and Franz *et al.* (U.S. Patent No. 5,797,873).

The Examiner states that Podszun teaches employing metal oxides and Franz teaches radio-opaque solid filler (zirconium dioxide), thus it would have been obvious to one skilled in the art “to utilize the zirconium dioxide of Franz et al in Podszun since Podszun teaches employing metal oxides and since the use of radio-opaque solid filler in polymeric compositions for medical applications in order to check the repaired part of a human body such as bone or teeth with X-ray machine is a routine practice in the art.”

Franz does not remedy the deficiencies of Podszun. Franz teaches a bone cement that includes an active compound such as methotrexate. As taught at column 5, lines 20-37 and in the Example of the cited reference, the bone cement is formed by combining a solid component comprising polymer of acrylic and/or methacrylic acid esters, e.g., PMMA/PMA copolymer, with a liquid component comprising an acrylic and/or methacrylic acid ester monomer. As discussed at column 5, lines 24-29 and column 6, lines 43-47 of Franz, it is the powder component of Franz that comprises X-ray contrast media and hydroxyapatite.

Franz does not disclose or suggest a material wherein at least a portion of the filler is present in regions occupied by polymerized liquid component. There is no teaching and no suggestion in the cited document for dispersing the filler within the polymer matrix to produce Applicants' claimed materials. Furthermore, Franz neither recognizes nor addresses problems related to the particle size of filler employed. The reference also does not recognize or address problems related to aggregation or agglomeration of filler particles. There is no recognition or appreciation in the cited document that well dispersed, ultrafine particles may confer advantageous properties to a bone cement.

Neither Podszun nor Franz, alone or in combination, discloses or suggests nanoencapsulated solid filler wherein at least a portion of the filler is present in regions occupied by polymerized liquid component and is dispersed within the polymer matrix resulting in the nanocomposite surgical material as claimed by the Applicants.

Reconsideration and withdrawal of this rejection are respectfully requested.

Rejection of Claims 1-20 under 35 U.S.C. § 103(a)

Claims 1-20 were rejected under 35 U.S.C. § 103(a) as obvious over Franz *et al.* (U.S. Patent No. 5,797,873) in view of Mathiowitz *et al.* (U.S. Patent No. 6,143,211) and Jiang *et al.* (U.S. Patent No. 5,847,046).

The Examiner implies that the difference between the present invention and Franz is the nanoencapsulated filler and biodegradable polymer matrix. The Examiner states that Mathiowitz teaches nano- and microencapsulated filler and that Jiang teaches a biodegradable polymer mix. The Examiner reasons that

[i]t would have been obvious to one skilled in that at the time of invention to utilize said nanoencapsulated filler of Mathiowitz et al in Franz et al since Franz et al teach employing particle size of below 100 μ m encompassing nanometers and since Mathiowitz et al teach the advantage (such as instant or controlled release on a site) of using nanoencapsulated filler, and further to utilize a biodegradable polymer mix taught by Jiang et al in Franz et al and Mathiowitz et al thereof since the use of a biodegradable polymer matrix such as polyactic acid or polyglycolic acid in implantable drug depots is well known as taught by Jiang et al absent showing otherwise.

Applicants respectfully disagree. As with Podszon and Franz, discussed above, there is no disclosure or suggestion in either Mathiowitz or Jiang of a nanocomposite surgical material that comprises a polymer matrix and a nanoencapsulated solid filler dispersed within the polymer matrix to produce a composite surgical material having an average matrix ligament thickness of less than 1000 nanometers, nor of a uniformly dispersed solid filler, wherein at least a portion of the filler is present in regions occupied by polymerized liquid component. Therefore, neither Mathiowitz nor Jiang remedy the deficiencies of Franz, taken separately or in combination.

Reconsideration and withdrawal of this rejection are respectfully requested.

CONCLUSION

In view of the above amendments and remarks, it is believed that all claims are in condition for allowance, and it is respectfully requested that the application be passed to issue. If the Examiner feels that a telephone conference would expedite prosecution of this case, the Examiner is invited to call the undersigned.

Respectfully submitted,

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